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**KARMANOS**  
CANCER INSTITUTE

*Wayne State University | Detroit Medical Center*

January 31, 2006

Norma Hagenow, Chairperson  
Certificate of Need Commission  
Michigan Department of Community Health  
Lewis Cass Building  
320 South Walnut Street  
Lansing, Michigan 48913

Dear Commissioner Hagenow:

Thank you the opportunity to share the Karmanos Cancer Institute's views on bone marrow transplant (BMT) programs in Michigan.

The current BMT standards are more than two decades old and should be updated to ensure continued, unduplicated access to the best available and affordable patient care. The Karmanos Cancer Institute has prepared the attached summary of issues regarding existing BMT centers and the lack of justification for any new centers.

BMT programs are enormously expensive to initiate, maintain and properly administer. There are two National Cancer Institute-designated comprehensive cancer centers in Michigan (Karmanos and the University of Michigan), which are also the two highest-volume BMT centers in the state. We believe that to properly focus resources, ensure optimal patient outcomes and further the science of these procedures, BMT programs in Michigan should be directly linked to federally-designated comprehensive cancer research programs, the only potential exception being to accommodate the distance between the Grand Rapids area and the two main centers.

I trust the following position paper is helpful. Please contact me directly should you have any questions.

Sincerely,



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The Meyer L. Prentis Comprehensive Cancer  
Center of Metropolitan Detroit, operated by  
the Karmanos Cancer Institute, is one of 39  
nationally-designated comprehensive cancer centers.

## **Background**

In 1984, Governor James Blanchard issued a directive to establish designated organ transplant centers in the State of Michigan. The Michigan State Medical Society was charged with organizing transplant subcommittees for various organs: heart, kidney, liver, lung and bone marrow. Dr. Voravit Ratanatharathorn, an accomplished BMT specialist and now leader of the Institute's BMT program, was appointed to chair the BMT subcommittee, which drafted certificate of need criteria. The Detroit Medical Center and the University of Michigan were the first centers to successfully apply for BMT CoNs. Butterworth Hospital (now part of Spectrum Health) was next, its approval being based on the distance between Grand Rapids and either Ann Arbor or Detroit. Henry Ford Hospital in Detroit and Oakwood Hospital In Dearborn subsequently obtained CoNs for BMT programs, though the rationale for these approvals was less clear as there were already two other excellent bone marrow transplantation centers, with capacity, in a 45-mile radius (Karmanos and U-M).

The current BMT CoN standards are more than two decades old. BMT procedures and the science behind them have changed dramatically in that time. Indeed, the term "bone marrow transplant" is outdated – the more accurate terminology to describe these procedures being "stem cell transplantation." Also, in the past a major indication for transplantation was in the area of breast cancer, but in most cases that is no longer medically justified. The state's BMT CoN standards should be updated to reflect these medical and scientific realities as well as to focus costly health care resources and expertise on those BMT programs where clinical care is directly linked with groundbreaking cancer research. It is the Karmanos Cancer Institute's strong belief that BMT programs are not "boutique" clinical services through which community hospitals attempt to elevate their stature in cancer care. There is also more than sufficient capacity in Michigan's two existing university-based BMT programs and the geographically distinct program in Grand Rapids.

Determining whether another BMT/stem cell transplantation center is needed in southeastern Michigan must address three issues: access, quality and cost.

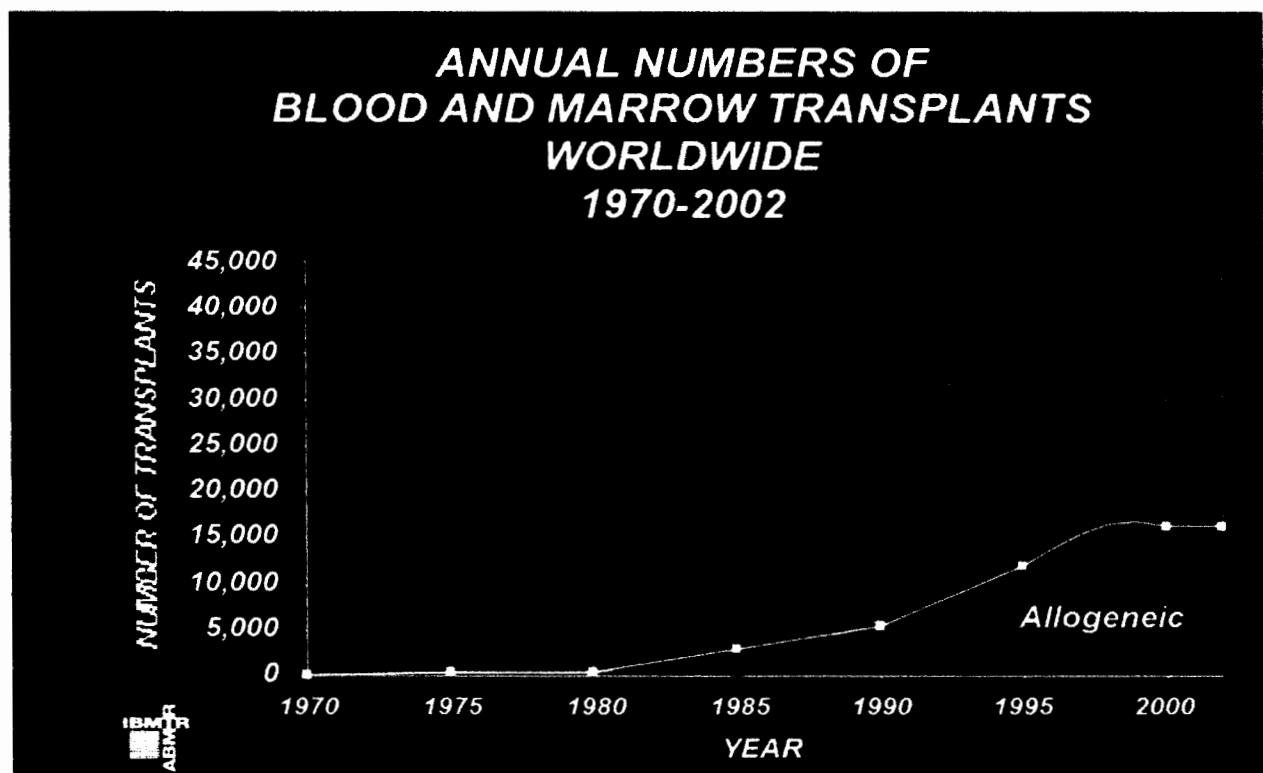
## **Access**

Considering that five stem cell transplant centers are located in Michigan, residents here have more accessibility to this service than virtually anywhere else in the nation. The two largest stem-cell transplant centers in the state, Karmanos and the University of Michigan (U-M), are now transplanting approximately 350 patients per year. Even at their current capacities, there have been no patient access difficulties regarding this service at these two centers. The volume of transplants conducted at the remaining three centers (Henry Ford, Oakwood and Spectrum) is approximately 100 per year. Those centers are clearly underutilized. As such, there is an overabundance of stem cell transplant services in the State of Michigan.

Access continued

Access to transplant services will not be a problem in the foreseeable future. While medical procedures for stem cell transplants have certainly changed, no new patient indications for BMT treatment have emerged during this time. Furthermore, the discoveries of new treatment options such as Gleevec have markedly decreased the demand for stem cell transplantation in patients with chronic myeloid leukemia. Because of alternative treatments, the growth of stem cell transplant procedures has slowed.

A study conducted by the Center for International Blood and Marrow Transplant Research (CIBMTR), estimated of the annual number of blood and marrow transplants worldwide. The numbers in this study were extrapolated from data compiled by the National Marrow Donor Program (NMDP), the European Blood and Marrow Transplant Group (EBMT), independent market surveys, U.S. hospital discharge data and data reported to the IBMTR. Study data shows that there has been a dramatic slowdown in the growth of autologous and allogeneic transplants. The drop in autotransplants was caused by a decrease in such procedures to treat breast cancer. The flattening in growth for allotransplants resulted from a decrease in procedures to treat chronic myelogenous leukemia.



## **Quality**

Most blood and marrow stem cell transplantation centers in the United States are located at academic medical centers. The immediate proximity of medical schools and affiliated research programs to transplant centers incubates the exchange of new technology and scientific knowledge leading to the ongoing potential for improvements in patient care. For example, the Karmanos Cancer Institute continues to expand services to collect umbilical cord blood in metro Detroit for stem cell transplantation under contract with the National Marrow Donor Program. A significant focus of the Institute's BMT program is utilizing umbilical cord blood to find genetic matches of stem cells to save the lives of minorities, especially African Americans.

Genetic matches for African Americans needing stem cell transplants are much more difficult than for Caucasian patients. The Institute's cord blood bank now stores about 500 units of which 78 percent are from donors of African American descent. Two percent of cord blood units in the Karmanos inventory are from donors of other under-represented minorities. The Institute operates the only cord blood stem cell bank in Michigan.

The most important quality assessment development for blood and marrow stem cell transplantation is voluntary accreditation through the Foundation for the Accreditation of Cellular Therapy (FACT). Of more than 200 stem cell transplant centers in North America, 128 are accredited by FACT, Karmanos and U-M being the only two in Michigan.

Ultimately, the purpose of accreditation is to ensure the delivery of high quality service to consumers. FACT demands very stringent criteria in every aspect of clinical stem cell transplantation ranging from organizational structure, staffing with qualified personnel, laboratory validation, quality control of stem cell procurement, stem cell processing, patient care, education and training of personnel and data reporting. The FACT assessment also factors in program leadership, clinical experience within the transplant team and the ability to produce scientific output.<sup>1</sup>

One of the indices of quality is the number of transplants performed. There have been two published studies linking outcome of stem cell transplantation to the volume of transplantation.<sup>2,3</sup> The analysis of outcomes is more complex than solid organ transplants due to heterogeneity of the underlying diseases for which stem cell transplantation is used.

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<sup>1</sup> C. Fred LeMaistre, Fausto R. Loberiza, Jr. What is quality in a transplant program? *Biology of Blood and Marrow Transplantation* 11:241-246, 2005.

<sup>2</sup> Mary M. Horowitz et al Should HLA-identical sibling bone marrow transplants for leukemia be restricted to large centers? *Blood* 79:2771-2774, 1992.

<sup>3</sup> Francesco Frasson et al Effect of centre on outcome of bone-marrow transplantation for acute myeloid leukaemia. *Lancet* 355:1393-1398, 2000.

## **Cost**

Blood and marrow stem cell transplantation programs require a huge investment of both manpower and financial resources. Financing the operation is costly, though far less difficult than assembling a qualified transplant team. There are few physicians trained as specialists in stem cell transplantation. Laboratory or research-trained doctors are even harder to come by. Basic science training and mandatory rotation through a transplant service during fellowship are merely starting points in the long road of becoming a qualified clinician in stem cell transplantation. Another significant cost factor is that BMT-specific training of nursing personnel and organizing a cohesive, effective team takes at least two years to accomplish. Also, a processing laboratory functioning to FACT standards must be established to handle stem cells for clinical use. This is an additionally costly operation since it is a task-specific laboratory that realistically cannot be used for anything else. True economies of scale in this regard can only be realized in clinical environments combining these many interrelated components through which more transplants will drive down the cost per procedure of stem cell procurement and processing.

New applicants for stem cell transplant center CoNs often do not conduct a thorough market study to initiate this service. A notable exception was St. John Hospital in Detroit, which, several years ago, was interested in establishing a BMT program and commissioned a market study and financial analysis as a precursor to applying for a CoN. The outcome of this study was that there was no market for an additional BMT center in southeastern Michigan, which, along with notable cost factors, led St. John to abandon the idea.

## **Conclusion**

The existing stem cell transplantation centers in Michigan are operating under capacity with two of the programs – at federally-designated comprehensive cancer centers – conducting the vast majority of BMT procedures. The three other community hospital based programs conduct significantly fewer. There is available capacity across the system, including at U-M and Karmanos.

Operating stem cell transplant programs unconnected to cancer research or directly related programs to benefit patients such as an umbilical cord blood program misallocates capital resources and clinical personnel. It is unlikely that the community hospital BMT programs in Michigan can attain or maintain FACT accreditation as these are not fully cohesive, integrated stem cell transplant centers. There is little bottom line financial wisdom in operating BMT programs at community hospitals beyond an intangible prestige factor.

Michigan's CoN standards for stem cell transplants should be updated to reflect these realities and focus resources on the unduplicated provision of limited BMT resources, perhaps through establishing enforceable volume requirements on existing programs and restricting the expansion of transplant centers.